K113403

FEB 14 2012

GE Healthcare

510(k) Premarket Notification Submission
Discovery IGS 730

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date Summary was Prepared:	November 10th, 2011
Submitter:	GE Healthcare GE Medical Systems, SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE T: +33-(0)1-30-70-47-41
Primary Contact Person:	Michel Genuer GE Healthcare (GE Medical Systems, SCS) Regulatory Affairs Leader, 283 RUE DE LA MINIERE 78530 BUC – FRANCE T: +33-(0)1-30-70-47-41 Email:michel.genuer@ge.com
Secondary Contact Person:	Carol Alloian Regulatory Affairs Leader, GE Healthcare 9900 W innovation drive Wauwatosa, WI, USA, 53226-4856 T: (847) 244-8327 F: (847) 589-8524 Email: carol.alloian@ge.com
Device/Trade Name:	GE Discovery IGS angiographic, fluoroscopic X- ray systems
Common/Usual Name:	angiographic, fluoroscopic X- ray system
Regulation Description: Regulation number: Product Code: Class:	Angiographic X- ray system 892.1600. 90 IZI, OWB, JAA II
Predicate Device(s):	K111209: INTEGRATED INNOVA - S5I SYSTEM OPTION GE Medical Systems K090745 : Siemens Artis Zee
Device Description:	The proposed device, Discovery IGS 730 is an X-ray angiographic system with a 30cm detector size. The proposed device introduces a

	new fixed C arm positioner that will be the basis of the Discovery IGS X-ray angiographic systems platform. The proposed device will be offered with 2 product configurations, Interventional and OR configuration. The indications for use are expanded to include image-guided surgical procedures and open surgery procedures for the OR configuration of the product. The X-ray tube, the collimator, the X-ray power unit, the flat panel, the X-ray control and image processing chain are the same as the GE Innova systems.
Intended Use: Indications for Use:	The angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures. Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures.
Technology:	The proposed Discovery IGS 730 system employs the same fundamental scientific technology as its predicate devices.
Determination of Substantial Equivalence:	<u>Summary of Non-Clinical Tests:</u> Non-clinical verification and validation tests were performed to verify and validate the system functionally for the intended use. The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Testing on unit level (Module verification) • Integration testing (System verification) • Performance testing (Verification) • Safety testing (Verification) • Simulated use testing (Validation) The Discovery IGS 730 system is designed in compliance with voluntary standards as detailed in Section 9 of this premarket submission. Verification and Validation (V&V) was performed and passed.

	Summary of Clinical Tests: The subject of this premarket submission, Discovery IGS 730, did not require clinical studies to support substantial equivalence in the intended clinical environment.
Conclusion:	GE Healthcare considers the Discovery IGS 730 to be as safe and effective as its predicates devices, and its performances to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Michael Genuer
Regulatory Affairs Leader
GE Healthcare
GE Medical System SCS
283 Rue de la Miniere
78530 BUC
FRANCE

JUL 30 2012

Re: K113403
Trade/Device Name: Discover IGS 730
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and IZI
Dated: November 10, 2011
Received: November 17, 2011

Dear Mr. Genuer:

This letter corrects our substantially equivalent letter of February 14, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): To Be Assigned

Device Name: Discovery IGS 730

Indications for Use:

The angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for cardiovascular, vascular and non-vascular, diagnostic and interventional procedures.
Additionally, with the OR table, the angiographic X-ray systems are indicated for use in generating fluoroscopic and rotational images of human anatomy for image-guided surgical procedures. The OR table is suitable for interventional and surgical procedures.

Prescription Use_X__ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel
(Division Sign-Off)
Division of Neurological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113403